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Date: May 9, 2005

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Re: Applicant: Kieran P.J. Murphy
U.S. Pat. App. Serial No. 09/594,685
Filed: June 16, 2000
For: APPARATUS FOR STRENGTHENING VERTEBRAL BODIES

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Client No: 8627/405 (PA-5281)

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PAPER FILED HEREWITH BY FACSIMILE:

PETITION UNDER 37 CFR 1.181 TO REVIEW DENIAL OF ENTRY OF AMENDMENT

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RAYMOND W. GREEN
Registered Representative

Signature

Date of Signature: May 9, 2005

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PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kieran P. J. Murphy	:	Cook Case PA-5281
Serial No.:	09/594,685	:	
Filed:	June 16, 2000	:	Group Art Unit: 3732
For:	APPARATUS FOR STRENGTHENING VERTEBRAL BODIES	:	Examiner: Eduardo C. Robert

PETITION UNDER 37 CFR 1.181
TO REVIEW
DENIAL OF ENTRY OF AMENDMENT

Mail Stop AF
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Petition Under 37 CFR 1.127 and 1.181 to review the denial, in the Advisory Action of March 10, 2005, of the entry of the Amendment filed February 10, 2005. In the event that a petition fee is due, please charge the fee to Applicant's Attorney's Deposit Account No. 23-1925.

CONTENTS

STATEMENT OF FACTS

1. After a first Final Rejection and a timely first Notice of Appeal, a timely first Appeal Brief was filed in this Application on January 12, 2004.

2. A non-final Office Action was mailed on March 24, 2004. In the Office Action of March 24, 2004, the Examiner reopened prosecution, withdrew two references, applied one reference not previously applied, maintained one rejection, withdrew one rejection, modified one rejection, added one rejection, and invited a reply under 37 CFR 1.111 to the Office Action.

3. In response to the Office Action of March 24, 2004, Applicant filed a timely Amendment on July 27, 2004, together with an expert Declaration Under 37 CFR 1.132 by the inventor, who is a medical doctor, traversing grounds of rejection. The Amendment maintained Claims 1-21 as presented previously, and added new Claims 22 and 23.

4. The Amendment and Declaration filed on July 27, 2004, have been entered. A copy of the claims submitted on July 27, 2004, is attached as Appendix A.

5. A Final Rejection in this Application was mailed November 15, 2004. In the Final Rejection, the Examiner stated, *inter alia*, that:

a. Claims 22 and 23 were considered indefinite and rejected under 35 USC 112, second paragraph, in that it was unclear whether the recited components were present in the first and second tray in combination, or if each of the first and second trays contained the recited components; but that for examination purposes, the claims had been construed to recite that each of the first and second trays contained the recited components. (Final Rejection of November 15, 2004, page 2.)

b. The recitation of "vertebroplasty" components was considered to be functional, and the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus. (Final Rejection of November 15, 2004, pages 5-6, page 7.) (The Examiner therefore gave no weight to the recitation of "vertebroplasty" components in the claims.)

c. In the Declaration filed July 24, 2004, the expert declarant states that a syringe and needle for injecting anesthetic are general surgical components, but in Applicant's claims (for example, Claim 22), a local anaesthesia injection needle is considered a vertebroplasty injection component. (Final Rejection of November 15, 2004, pages 6-7.)

d. Claims 22 and 23 (as filed July 27, 2004) would be allowable if rewritten to overcome the rejection under 35 USC 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims. (Final Rejection of November 15, 2004, page 10.)

6. A timely Amendment and Notice of Appeal in response to the Final Rejection of November 15, 2004, were filed on February 10, 2005. A copy of the claims submitted February 10, 2005, is attached as Appendix B. In the Amendment filed February 10, 2005:

a. No amendments to the Specification were made.

b. Claims 1, 17, 20, 21, 22 and 23 were proposed to be amended by changing recitations of "vertebroplasty components" to recite "vertebroplasty and surgical components".

c. Dependent Claims 22 and 23 were proposed to be rewritten in independent form, to include all of the limitations of the base claim and any intervening claims.

d. Claims 22 and 23 were also proposed to be amended to recite that each of the first and second trays contained the recited components.

7. The amendment changing recitations of "vertebroplasty components" to "vertebroplasty and surgical components" was proposed to remove a point of contention, although it was totally unnecessary, and did not change the scope of the claims, because vertebroplasty is a type of surgical procedure. Hence, vertebroplasty components *are* surgical components – specialized surgical components.

8. An Advisory Action was mailed in this Application on March 10, 2005. In the Advisory Action, the Examiner stated, *inter alia*, that:

a. The proposed Amendment filed February 10, 2005, would not be entered, because it was deemed to raise new issues that would require further consideration and/or search, and because it was deemed to raise the issue of new matter.

b. For purposes of appeal, the proposed amendment would not be entered, and Claims 1-23 would be continued to be rejected.

c. The Amendment of Claims 1, 17, 20, 21, 22 and 23, changing recitations of "vertebroplasty components" to recite "vertebroplasty and surgical components", was considered to change the scope of the claims, and would require further consideration. The Examiner explained that the scope of the claims was considered to be changed by changing what Applicant considered to be "vertebroplasty components", as some of the components recited in the claims were previously characterized as "vertebroplasty components", but they are not so characterized in the proposed claims. The Examiner also stated that this amendment introduces the question of new matter and would require further consideration.

9. A Request for Reconsideration was filed on April 5, 2005, in contemplation of this Petition Under 37 CFR 1.181, requesting similar relief. Applicant's Attorney has not, as of the filing of this Petition, learned of the Request for Reconsideration being decided. Applicant's second Appeal Brief was filed April 13, 2005.

ACTION REQUESTED

The Director is requested to review the denial of entry of the Amendment filed February 10, 2005, and order that it be entered. (Upon entry of the Amendment; the Examiner is requested to reconsider the allowability of the pending claims, in view of entry of the Amendment; and to notify Applicant of the entry of the Amendment and of the status of the claims for purpose of appeal.)

ARGUMENT

1. THE ONLY OBJECTIONS TO THE ENTRY OF THE AMENDMENT EXPRESSED BY THE EXAMINER ARE ALLEGED CHANGES TO THE SCOPE OF THE CLAIMS, THE REQUIREMENT FOR FURTHER CONSIDERATION AND/OR SEARCH, AND ALLEGED NEW MATTER.

The Amendment filed February 10, 2005, proposed three changes to the Claims:

a. Claims 1, 17, 20, 21, 22 and 23 were amended by changing recitations of "vertebroplasty components" to recite "vertebroplasty and surgical components".

b. Dependent Claims 22 and 23 were rewritten in independent form, to include all of the limitations of the base claim and any intervening claims.

c. Claims 22 and 23 were also amended to recite that each of the first and second trays contained the recited components.

The Examiner has raised no objection to the second and third changes. The third change is in fact a clarification to explicitly state more clearly what was the intended scope of the claims, and which was the scope assumed by the Examiner for purposes of examination, namely that each of the first and second trays contained the recited components.

The second change was invited by the Examiner, when he said that Claims 22 and 23 (as filed July 27, 2004) would be allowable if rewritten to overcome the rejection under 35 USC 112, second paragraph (i.e., to clarify that each of the first and second trays contained the recited components), and to include all of the limitations of the base claim and any intervening claims. Now that Applicant has complied with the suggestion to re-write Claims 22 and 23 as indicated by the Examiner, however, amended Claims 22 and 23 have not been entered, and the previously presented Claims 22 and 23 continue to be rejected. The only reasons given for not entering the amendment and allowing Claims 22 and 23 are that the Amendment would change the scope of the claims by adding "and surgical", that the Amendment would require further consideration and/or search, and that the Amendment would raise the issue of new matter.

2. THE AMENDMENT DOES NOT CHANGE THE SCOPE OF THE CLAIMS.

Two claims are of the same scope if they claim identical subject matter, *i.e.*, unless there is subject matter that is covered by one claim, but which was not covered by the other claim, then the two claims are identical in scope. *See* MPEP § 804 ILA, page 800-20 (8th ed. August 2001).

The Examiner asserts that Claims 1, 17, 20, 21, 22 and 23 as proposed February 10, 2005, differ in scope from Claims 1, 17, 20, 21, 22 and 23, respectively, as presented in the Amendment filed July 27, 2004. However, there is *no change* in the elements recited in the claims. The only relevant change is how the elements are characterized. For example:

Claim 21 as presented July 27, 2004, recited "A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle."

In the Final Rejection of November 15, 2004, the Examiner pointed out that some of the components recited (such as "a local anaesthesia injection needle") were not "vertebroplasty components", but rather general surgical components, and were so characterized in the Declaration filed July 24, 2004. Responsive to this criticism of the claim, in the Amendment filed February 10, 2004, the preamble was proposed to be amended to recite "A tray of vertebroplasty and surgical components ...". Claim 21 as so proposed to be amended was therefore in better form for appeal, because the Claim as proposed to be amended was not subject to the criticism that the recitation "A tray of vertebroplasty components ..." was mis-descriptive of the components recited, to the extent that some of the components were general surgical

components, rather than "vertebroplasty components", *i.e.*, specialized components for use in performing vertebroplasty surgery, but not used in other types of surgery.

The amendment changing recitations of "vertebroplasty components" to "vertebroplasty and surgical components", however, was totally unnecessary, and did not change the scope of the claims, because vertebroplasty is a type of surgical procedure. Hence, vertebroplasty components *are* surgical components – specialized surgical components.

And the list of components recited in Claim 21 was not changed. There is no combination of components that would infringe Claim 21 as presented July 27, 2004, that would not also infringe Claim 21 as proposed to be amended on February 10, 2005. Likewise, there is no combination of components that would infringe Claim 21 as proposed to be amended on February 10, 2005, that would not also infringe Claim 21 as presented July 27, 2004.

The same sort of analysis could be made with respect to the other claims amended to recite "vertebroplasty and surgical components ...". Specifically:

There is no combination of components that would infringe Claim 1 as presented July 27, 2004, that would not also infringe Claim 1 as proposed to be amended on February 10, 2005, and there is no combination of components that would infringe Claim 1 as proposed to be amended on February 10, 2005, that would not also infringe Claim 1 as presented July 27, 2004.

There is no combination of components that would infringe Claim 17 as presented July 27, 2004, that would not also infringe Claim 17 as proposed to be amended on February 10, 2005, and there is no combination of components that would infringe Claim 17 as proposed to be amended on February 10, 2005, that would not also infringe Claim 17 as presented July 27, 2004.

There is no combination of components that would infringe Claim 20 as presented July 27, 2004, that would not also infringe Claim 20 as proposed to be amended on February 10, 2005, and there is no combination of components that would infringe Claim 20 as proposed to be amended on February 10, 2005, that would not also infringe Claim 20 as presented July 27, 2004.

There is no combination of components that would infringe Claim 22 as presented July 27, 2004, that would not also infringe Claim 22 as proposed to be amended on February 10, 2005, and there is no combination of components that would infringe Claim 22 as proposed to be

amended on February 10, 2005, that would not also infringe Claim 22 as presented July 27, 2004.

There is no combination of components that would infringe Claim 23 as presented July 27, 2004, that would not also infringe Claim 23 as proposed to be amended on February 10, 2005, and there is no combination of components that would infringe Claim 23 as proposed to be amended on February 10, 2005, that would not also infringe Claim 23 as presented July 27, 2004.

So there is no change in the scope of the claims as presented July 27, 2004, and as proposed to be amended on February 10, 2005. Correcting the description to characterize a local anaesthesia injection needle (and other components not specific to vertebroplasty) as *surgical* components, rather than as *vertebroplasty* components, does not change the nature of the local anaesthesia injection needle or other components, or alter the scope of the claims.

3. THE AMENDMENT SHOULD NOT REQUIRE FURTHER CONSIDERATION OR SEARCH.

The Examiner says that the proposed claims would require further consideration and/or search. It is not seen how this could be the case, if the claims have been properly considered previously.

With respect to "further search", the Examiner has asserted all along that the recitation of "vertebroplasty components" indicates a functionality or an intended use, and that the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus. So the Examiner has not cited references that show "vertebroplasty components", but has rather relied on references such as Lazarus (which shows general surgical needles) to meet the recitation of "vertebroplasty injection components". So if the Examiner now thinks that he should consider the recitation "vertebroplasty and surgical components" in searching for prior art, he should have considered "vertebroplasty components" before. Either he did not do so, or he was unable to find any relevant prior art that recited "vertebroplasty components" before. The Examiner should not refuse to enter an amendment either because he

did not consider the recitation of "vertebroplasty components" important before, or because he was unable to find any relevant patents that recited "vertebroplasty components" before.

With respect to "further consideration", similar arguments apply. The Examiner should consider, of course, if "vertebroplasty and surgical components" is a better description of what follows than "vertebroplasty components". If so, the proposed amendment improves to form of the claims for purpose of appeal, removes a potential criticism of the claims, and should be entered. However, as discussed above, the amendment does not change the scope of the claims, because all of the same elements, and no more, are still present in each of the respective claims. So it is not seen what kind of consideration the Examiner would give to the claims, that he should not have given before when the claims recited "vertebroplasty components".

4. THE AMENDMENT DOES NOT CONSTITUTE NEW MATTER.

"In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites [new matter]." MPEP § 706.03(o), page 700-69 (8th ed., Rev. 2, May 2004). However, the Amendment proposed on February 10, 2005, did not add subject matter not disclosed in the original application.

"An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but would also recognize the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971)." MPEP § 2163 I.B, *New or Amended Claims*, page 2100-167 (8th ed., Rev. 2, May 2004); MPEP § 2163.07, page 2100-183 (8th ed., Rev. 2, May 2004). Changing "vertebroplasty components" to "vertebroplasty and surgical components" corrects an obvious error, as one skilled in the art would not only recognize the existence of the error in the specification, but would also recognize the appropriate correction. It therefore does not constitute new matter.

"The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of

the invention as now claimed. See, e.g., *Vas-Cath, Inc. [v. Mahurkar]*, 935 F.2d [1555] at 1563-64, 19 USPQ2d [1111] at 1117 [(Fed. Cir. 1991)]." MPEP § 2163 I.B, *New or Amended Claims*, page 2100-168 (8th ed., Rev. 2, May 2004). The present specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, applicant was in possession of the invention as proposed to be claimed in the Amendment filed February 10, 2005.

"An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. [Citing cases.]" MPEP § 2163 II.A.3 (a), page 2100-170 (8th ed., Rev. 2, May 2004). One skilled in the art would recognize that Applicant had possession of the claimed invention, even when "vertebroplasty and surgical components" are identified as "vertebroplasty components".

"The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention claimed by the claims. See *[In re] Wertheim*, 541 F.2d [257] at 263, 191 USPQ [90] at 97 [(CCPA 1976)]." MPEP § 2163 II.A.3 (b), page 2100-175 (8th ed., Rev. 2, May 2004). The Examiner has made no such showing.

"An objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.' *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)." MPEP § 2163.02, page 2100-177 (8th ed., Rev. 2, May 2004). One skilled in the art would recognize that Applicant invented what is claimed, even when "vertebroplasty and surgical components" are identified as "vertebroplasty components".

"Mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible. *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973)." MPEP § 2163.07, page 2100-183 (8th ed., Rev. 2, May 2004). Rephrasing "vertebroplasty components" as "vertebroplasty and surgical components", without changing the components recited, does not constitute new matter.

5. THE AMENDMENT PLACES THE CLAIMS IN BETTER FORM FOR APPEAL.

The Amendment proposed February 10, 2005, places the claims in better form for appeal, by rewriting dependent Claims 22 and 23 in independent form, to include all of the limitations of the base claim and any intervening claims, as requested by the Examiner, to make them allowable, regardless of whether the base claim is allowable.

The Amendment proposed February 10, 2005, places the claims in better form for appeal, by amending Claims 22 and 23 to clearly recite that each of the first and second trays contained the recited components, which was the situation always intended to be conveyed, and which was assumed by the Examiner for purposes of examination.

The Amendment proposed February 10, 2005, places the claims in better form for appeal, because the Claims as proposed to be amended were not subject to the criticism that the recitation "vertebroplasty components ..." was mis-descriptive of the components recited, to the extent that some of the components were general surgical components, rather than "vertebroplasty components", *i.e.*, specialized components for use in performing vertebroplasty surgery, but not used in other types of surgery.

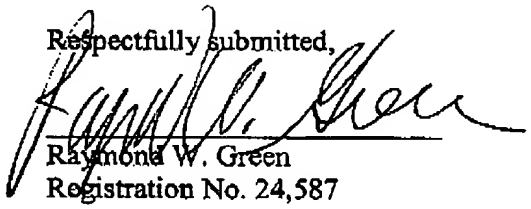
CONCLUSION

The Amendment filed July 27, 2004, was entered. In the Final Rejection of November 15, 2004, the Examiner (1) found two claims (22 and 23) indefinite, stated his assumption of how they should be interpreted, and stated that the claims would be allowable if amended to overcome the ambiguity and recite all the features of the base claims from which they depended; (2) stated why he gave no weight to the recitation of "vertebroplasty" components in the claims; and (3) noted that some of the claims recited general surgical components. The Amendment filed February 10, 2005, re-wrote Claims 22 and 23 to overcome the ambiguity and recite all the features of the base claims from which they depended; and proposed to amend Claims 1, 17, 20, 21, 22 and 23 by changing recitations of "vertebroplasty components" to recite "vertebroplasty and surgical components". The Advisory Action of March 10, 2005, stated that the proposed Amendment would not be entered, because it was deemed to change the scope of the claims,

because it was deemed to raise new issues that would require further consideration and/or search, and because it was deemed to raise the issue of new matter. However, the proposed Amendment did not *in fact* change the scope of the claims, raise new issues that would require further consideration and/or search, or constitute new matter.

This Application has already been delayed in excess of one year in resolution of its allowability, because the references and rejections applied by the Examiner in the first Final Rejection were insufficient to bear the scrutiny of an appeals conference, with the result that Applicant's real party in interest must now bear the additional expense and delay of preparing the second appeal brief (filed April 13, 2005), discussing the references and rejections applied by the Examiner in the second Final Rejection. Applicant and Applicant's real party in interest should not be subjected to the further expense and delay caused by the Examiner's improper refusal to enter the proposed Amendment filed February 10, 2005.

Respectfully submitted,



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APPENDIX A (Claims presented July 27, 2004)

Claim 1 (previously presented): A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia assembly for producing a reversible loss of sensation in a surgical area proximate to a vertebral body;

a bone cement assembly for preparation of a hardenable liquid biomaterial for strengthening said vertebral body;

a surgical cutting instrument for providing cutaneous incision in said surgical area proximate to said vertebral body; and

a device for injection of said hardenable liquid biomaterial into said vertebral body.

Claim 2 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one container of a local anaesthesia.

Claim 3 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration syringe.

Claim 4 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration needle.

Claim 5 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia injection needle.

Claim 6 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one container of a liquid monomer.

Claim 7 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration needle.

Claim 8 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration syringe.

Claim 9 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one mixing bowl.

Claim 10 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one mixing spatula.

Claim 11 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one container of polymer powder.

Claim 12 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes an opacifier.

Claim 13 (previously presented): The tray according to claim 11, wherein said polymer powder is methylmethacrylate.

Claim 14 (previously presented): The tray according to claim 11, wherein said polymer powder in said hardenable liquid biomaterial is from about five grams to about forty grams of methylmethacrylate.

Claim 15 (previously presented): The tray according to claim 11, wherein said surgical cutting instrument is a scalpel.

Claim 16 (previously presented): The tray according to claim 11, wherein said device for injection is a vertebroplasty needle.

Claim 17 (previously presented): A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body.

Claim 18 (previously presented): The kit according to claim 17, wherein said first tray and said second tray are individually assembled and packaged.

Claim 19 (previously presented): The kit according to claim 18, wherein said first tray and said second tray are sterile until use in performing vertebroplasty.

Claim 20 (previously presented): A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;
a local anaesthesia aspiration syringe;
a local anaesthesia aspiration needle;
a local anaesthesia injection needle;
a liquid monomer;
a monomer aspiration needle;
a monomer aspiration syringe;
a mixing bowl;
a mixing spatula;
a polymer powder;
an opacifier;
a scalpel; and
a vertebroplasty needle.

Claim 21 (previously presented): A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.

Claim 22 (new): The kit according to claim 17, wherein the vertebroplasty injection components comprise:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a liquid monomer;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a polymer powder;

an opacifier;

a scalpel; and

a vertebroplasty needle.

Claim 23 (new): The kit according to claim 17, wherein the vertebroplasty injection components comprise:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.

APPENDIX B (Claims presented February 10, 2005)

Claim 1 (currently amended): A tray of vertebroplasty and surgical components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia assembly for producing a reversible loss of sensation in a surgical area proximate to a vertebral body;

a bone cement assembly for preparation of a hardenable liquid biomaterial for strengthening said vertebral body;

a surgical cutting instrument for providing cutaneous incision in said surgical area proximate to said vertebral body; and

a device for injection of said hardenable liquid biomaterial into said vertebral body.

Claim 2 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one container of a local anaesthesia.

Claim 3 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration syringe.

Claim 4 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration needle.

Claim 5 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia injection needle.

Claim 6 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one container of a liquid monomer.

Claim 7 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration needle.

Claim 8 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration syringe.

Claim 9 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one mixing bowl.

Claim 10 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one mixing spatula.

Claim 11 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one container of polymer powder.

Claim 12 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes an opacifier.

Claim 13 (previously presented): The tray according to claim 11, wherein said polymer powder is methylmethacrylate.

Claim 14 (previously presented): The tray according to claim 11, wherein said polymer powder in said hardenable liquid biomaterial is from about five grams to about forty grams of methylmethacrylate.

Claim 15 (previously presented): The tray according to claim 11, wherein said surgical cutting instrument is a scalpel.

Claim 16 (previously presented): The tray according to claim 11, wherein said device for injection is a vertebroplasty needle.

Claim 17 (currently amended): A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection and surgical components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection and surgical components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body.

Claim 18 (previously presented): The kit according to claim 17, wherein said first tray and said second tray are individually assembled and packaged.

Claim 19 (previously presented): The kit according to claim 18, wherein said first tray and said second tray are sterile until use in performing vertebroplasty.

Claim 20 (currently amended): A tray of vertebroplasty and surgical components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;
a local anaesthesia aspiration syringe;
a local anaesthesia aspiration needle;
a local anaesthesia injection needle;
a liquid monomer;
a monomer aspiration needle;
a monomer aspiration syringe;
a mixing bowl;
a mixing spatula;
a polymer powder;
an opacifier;
a scalpel; and
a vertebroplasty needle.

Claim 21 (currently amended): A tray of vertebroplasty and surgical components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.

Claim 22 (currently amended): A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection and surgical components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection and surgical components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body [The kit according to claim 17],

wherein said first tray and said second tray each contain the following vertebroplasty injection and surgical components [comprise]:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a liquid monomer;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a polymer powder;

an opacifier;

a scalpel; and

a vertebroplasty needle.

Claim 23 (currently amended): A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection and surgical components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection and surgical components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body [The kit according to claim 17],

wherein said first tray and said second tray each contain the following vertebroplasty injection and surgical components [comprise]:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.